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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	**Application No.** 10/677,716	**Applicant(s)** SALAHIEH ET AL.
	Examiner Melanie Tyson	**Art Unit** 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-29* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1,3/04 & 6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 and 27 contain the trademark/trade name C-FLEX. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the material included in the elastomeric jacket and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (Patent No. 5,549,626).

Regarding claim 1, Miller et al. disclose an elongated shaft member (Figure 1, element 17), having a proximal section (19) and a distal section (20), and a braided member (column 4, line 48; the filter 13 is made by the "braiding" process) coupled to the distal section (20) of the elongated shaft member (17). Miller et al. further disclose the braided member (13) includes a plurality of filaments ("metal filaments"; column 4, lines 48-49) defining a radially expandable inner lumen (not labeled), wherein the plurality of filaments are configured to radially expand when axially compressed (radially-expandable filtering device; column 1, lines 6-7).

The preamble "for retrieving an intravascular device from a body lumen" is given limited weight and the device disclosed by Miller et al. is inherently capable of performing the function as claimed. Also, the phrase "configured to receive and encapsulate the intravascular device therein" is a functional limitation and the device disclosed by Miller et al. is inherently capable of performing the function as claimed. Since the device satisfies the claimed structural limitations and it expands to encapsulate and remove material from a body lumen (column 2, lines 33-35 and 52), the device disclosed by Miller et al. is inherently capable of retrieving and encapsulating an intravascular device from a body lumen.

Regarding claim 8, Miller et al. disclose the plurality of filaments comprise a polymeric material ("metallic or plastic," and plastic is a polymeric material; column 3, lines 45-47).

Regarding claim 9, Miller et al. disclose the plurality of filaments comprise a metal ("metallic"; column 3, lines 45-47).

4. Claims 1, 3, 10-12, 15, 17, 19, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Dubrul et al. (Patent No. 6,221,006 B1).

Regarding claim 1, Dubrul et al. disclose an elongated shaft member (Figure 8A, element 21), having a proximal section (not labeled) and a distal section (Figure 8B, element 32), and a braided member (column 14, lines 1-4; "multi-braided device" 20) coupled to the distal section (Figure 8B, element 32) of the elongated shaft member (21). Dubrul et al. further disclose the braided member (20) includes a plurality of filaments ("multi-stranded"; column 14, lines 3-4) defining a radially expandable inner lumen (22), wherein the plurality of filaments are configured to radially expand when axially compressed (see Figure 8B).

The preamble "for retrieving an intravascular device from a body lumen" is given limited weight and the device disclosed by Dubrul et al. is inherently capable of performing the function as claimed. Also, the phrase "configured to receive and encapsulate the intravascular device therein" is a functional limitation and the device disclosed by Dubrul et al. is inherently capable of performing the function as claimed. Since the device satisfies the claimed structural limitations and it expands to encapsulate and remove material from a body lumen (biologic or synthetic; column 2, lines 61-63), the device disclosed by Dubrul et al. is inherently capable of retrieving and encapsulating an intravascular device from a body lumen.

Regarding claim 3, Figure 8B shows the distal end (32) of the elongated shaft member (21) is flared.

Regarding claim 10, Dubrul et al. disclose an elastomeric jacket encasing at least part of the braided member ("elastomeric covering"; column 14, lines 9-11).

Regarding claim 11, Dubrul et al. disclose the elastomeric jacket includes silicone (column 12, line 50).

Regarding claim 12, Dubrul et al. disclose the elastomeric jacket includes urethane ("polyurethanes"; column 12, line 50).

Regarding claim 15, Dubrul et al. disclose an elongated shaft member (Figure 8A, element 21), having a proximal section (not labeled) and a distal section (Figure 8B, element 32), and a braided member (column 14, lines 1-4; "multi-braided device" 20) coupled to the distal section (Figure 8B, element 32) of the elongated shaft member (21). Dubrul et al. further disclose the braided member (20) includes a plurality of filaments ("multi-stranded"; column 14, lines 3-4) defining a radially expandable inner lumen (22), wherein the plurality of filaments are configured to radially expand when axially compressed (see Figure 8B). Dubrul et al. further disclose an elastomeric jacket encasing at least part of the braided member ("elastomeric covering"; column 14, lines 9-11).

The preamble "for retrieving an intravascular device from a body lumen" is given limited weight and the device disclosed by Dubrul et al. is inherently capable of performing the function as claimed. Also, the phrase "configured to receive and encapsulate the intravascular device therein" is a functional limitation and the device disclosed by Dubrul et al. is inherently capable of performing the function as claimed. Since the device satisfies the claimed structural limitations and it expands to encapsulate and remove material from a body lumen (biologic or synthetic; column 2, lines 61-63), the device disclosed by Dubrul et al. is inherently capable of retrieving and encapsulating an intravascular device from a body lumen.

Regarding claim 17, Figure 8B shows the distal end (32) of the elongated shaft member (21) is flared.

Regarding claim 19, Figure 8B shows the plurality of filaments are configured to radially expand when axially compressed.

Regarding claim 23, Dubrul et al. disclose the plurality of filaments comprise a polymeric material ("polymers"; column 14, line 6).

Regarding claim 24, Dubrul et al. disclose the plurality of filaments comprise a metal (column 14, line 6).

Regarding claim 25, Dubrul et al. disclose the elastomeric jacket includes silicone (column 12, line 50).

Regarding claim 26, Dubrul et al. disclose the elastomeric jacket includes urethane ("polyurethanes"; column 12, line 50).

5. Claims 4-7, 13, 18, 20-22, 27, and 29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dubrul et al.

Dubrul et al. disclose a device as described above, where the braided member is similar in configuration to the TRAP (another braided member disclosed by Dubrul et al.). Regarding claim 4, Dubrul et al. further disclose the plurality of filaments of the TRAP braid are arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis (a tubular braid that is formed by moving one system of yarn helically clockwise with respect to the axis and another helically counterclockwise; column 15, lines 9-11). Therefore, it is inherent that the plurality of filaments of the braided member described above is also arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange two sets of parallel helices wound in opposite directions about a common longitudinal axis as in the TRAP portion taught by Dubrul et al. in order to provide a balanced, torque-free fabric.

Regarding claim 5, Dubrul et al. disclose the TRAP braid is formed of multi-filar threads (a mesh of individual filaments called yarns; column 14, lines 44-45). Therefore, it is inherent that the plurality of filaments of the device described above is also formed of multi-filar threads. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a plurality of filaments comprising multi-filar threads as in the TRAP portion taught by Dubrul et al. in order to have sufficient strength for entrapping material.

Regarding claims 6-7, Dubrul et al. disclose platinum (a radiopaque material) may be used in the device described above. Dubrul et al. further discloses the TRAP braid may be formed of composite material (interweaving elastic and inelastic filaments; column 14, lines 44-47). Therefore, it is inherent that the plurality of filaments of the braided member described above is also formed of composite material. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a plurality of filaments comprising a composite material as in the TRAP portion taught by Dubrul et al. in order to create the particular characteristics desired (elastic, superelastic, etc.).

Regarding claim 13, Dubrul et al. disclose the device is a multi-stranded braided device that may be coated or encased in an elastomeric or other covering (column 14, lines 9-11). Dubrul et al. further discloses the elastomeric jacket (or covering) of the TRAP braid may include C-flex (column 14, line 35). Therefore, it is inherent that the elastomeric jacket of the device described above may also include C-flex. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an elastomeric jacket including C-flex as in the TRAP portion as taught by Dubrul et al. in order to prevent encapsulated material from passing through the filaments, while maintaining its elastic properties.

Dubrul et al. disclose a device as described above, where the braided member is similar in configuration to the TRAP (another braided member disclosed by Dubrul et al.). Regarding claim 18, Dubrul et al. disclose the plurality of filaments of the TRAP braid are arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis (a tubular braid that is formed by moving one system of yarn helically clockwise with respect to the axis and another helically counterclockwise; column15, lines 9-11). Therefore, it is inherent that the plurality of filaments of the device described above is also arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange two sets of parallel helices wound in opposite directions about a common longitudinal axis as in the TRAP portion taught by Dubrul et al. in order to provide a balanced, torque-free fabric.

Regarding claim 20, Dubrul et al. disclose the TRAP braid is formed of multi-filar threads (a mesh of individual filaments called yarns; column 14, lines 44-45). Therefore, it is inherent that the plurality of filaments of the device described above is also formed of multi-filar threads. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a plurality of filaments comprising multi-filar threads as in the TRAP portion taught by Dubrul et al. in order to have sufficient strength for entrapping material.

Regarding claims 21-22, Dubrul et al. disclose platinum (a radiopaque material) may be used in the device described above. Dubrul et al. further discloses the TRAP braid may be formed of composite material (interweaving elastic and inelastic filaments; column 14, lines 44-47). Therefore, it is inherent that the plurality of filaments of the braided member described above is also formed of composite material. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a plurality of filaments comprising a composite material as in the TRAP portion taught by Dubrul et al. in order to create the particular characteristics desired (elastic, superelastic, etc.).

Regarding claim 27, Dubrul et al. disclose the device is a multi-stranded braided device that may be coated or encased in an elastomeric or other covering (column 14, lines 9-11). Dubrul et al. further discloses the elastomeric jacket (or covering) of the TRAP braid may include C-flex (column 14, line 35). Therefore, it is inherent that the elastomeric jacket of the device described above may also include C-flex. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an elastomeric jacket including C-flex as in the TRAP portion as taught by Dubrul et al. in order to prevent encapsulated material from passing through the filaments, while maintaining its elastic properties.

Regarding claim 29, Regarding claim 15, Dubrul et al. disclose an elongated shaft member (Figure 8A, element 21), having a proximal section (not labeled) and a distal section (Figure 8B, element 32), and a braided member (column 14, lines 1-4; "multi-braided device" 20) coupled to the distal section (Figure 8B, element 32) of the elongated shaft member (21). Dubrul et al. further disclose the braided member is similar in configuration to the TRAP (another braided member disclosed by Dubrul et al.), in which the plurality of filaments of the TRAP braid are arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis (a tubular braid that is formed by moving one system of yarn helically clockwise with respect to the axis and another helically counterclockwise; column 15, lines 9-11). Therefore, it is inherent that the plurality of filaments of the braided member described above is also arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange two sets of parallel helices wound in opposite directions about a common longitudinal axis as in the TRAP portion taught by Dubrul et al. in order to provide a balanced, torque-free fabric.

The preamble "for retrieving an intravascular device from a body lumen" is given limited weight and the device disclosed by Dubrul et al. is inherently capable of performing the function as claimed. Also, the phrase "configured to receive and encapsulate the intravascular device therein" is a functional limitation and the device disclosed by Dubrul et al. is inherently capable of performing the function as claimed. Since the device satisfies the claimed structural limitations and it expands to encapsulate and remove material from a body lumen (biologic or synthetic; column 2, lines 61-63), the device disclosed by Dubrul et al. is inherently capable of retrieving and encapsulating an intravascular device from a body lumen.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. in view of Zadno-Azizi et al. (Publication No. 2002/0091407 A1).

Miller et al. disclose a device as described above, however, Miller et al. do not disclose the elongated shaft member includes polyether block amide. Like Miller et al., Zadno-Azizi et al. disclose a system for material containment in a lumen (paragraph 12). Unlike Miller et al., Zadno-Azizi et al. disclose the elongated shaft member (or catheter shaft) includes polyether block amide (paragraph 88) in order for the shaft to have sufficient structural integrity, or stiffness, to permit the catheter to be pushed through the vasculature to distal arterial locations without buckling or undesirable bending of the body (paragraph 88). Therefore, to include polyether block amide in the construction the elongated shaft member of Miller et al. as taught by Zadno-Azizi et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to prevent buckling of the device as it is pushed through the body lumen.

9. Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. in view of Anderson et al. (Publication No. 2002/0188314 A1).

Regarding claim 14, Dubrul et al. disclose a device as described above, however, Dubrul et al. do not disclose the elastomeric jacket includes a radiopaque material. Like Dubrul et al., Anderson et al. disclose a device for capturing and removing material from a lumen (paragraph 11). Unlike Dubrul et al., Anderson et al. disclose the elastomeric jacket (or polymeric compound that covers the device) may include (or be combined with) a radiopaque material (paragraph 60) in order to be able to view the device under fluoroscopy during a medical procedure (paragraph 12). Therefore, to include radiopaque material in the elastomeric jacket of Dubrul et al. as taught by Anderson et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to view the path and/or placement of the device during the procedure.

Regarding claim 28, Dubrul et al. disclose a device as described above, however, Dubrul et al. do not disclose the elastomeric jacket includes a radiopaque material. Like Dubrul et al., Anderson et al. disclose a device for capturing and removing material from a lumen (paragraph 11). Unlike Dubrul et al., Anderson et al. disclose the elastomeric jacket (or polymeric compound that covers the device) may include (or be combined with) a radiopaque material (paragraph 60) in order to be able to view the device under fluoroscopy during a medical procedure (paragraph 12). Therefore, to include radiopaque material in the elastomeric jacket of Dubrul et al. as taught by Anderson et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to view the path and/or placement of the device during the procedure.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. in view of Zadno-Azizi et al.

Dubrul et al. disclose a device as described above, however, Dubrul et al. do not disclose the elongated shaft member includes polyether block amide. Like Dubrul et al., Zadno-Azizi et al. disclose a system for material containment in a lumen (paragraph 12). Unlike Dubrul et al., Zadno-Azizi et al. disclose the elongated shaft member (or catheter shaft) includes polyether block amide (paragraph 88) in order for the shaft to have sufficient structural integrity, or stiffness, to permit the catheter to be pushed through the vasculature to distal arterial locations without buckling or undesirable bending of the body (paragraph 88). Therefore, to include polyether block amide in the construction the elongated shaft member of Dubrul et al. as taught by Zadno-Azizi et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to prevent buckling of the device as it is pushed through the body lumen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
August 22, 2006

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SUPERVISORY PATENT EXAMINER
8/25/06